

## Patent Claims

1. Method for the early diagnosis and diagnosis, for  
the prognosis and the assessment of the severity  
5 and for the therapy-accompanying assessment of the  
course of sepsis and sepsis-like systemic  
infections and for the estimation of the risk of a  
sepsis risk patient through the formation of a  
sepsis, characterized in that the presence and/or  
10 amount of anti-asialo-G<sub>M1</sub> antibodies (anti-AG<sub>M1</sub>  
antibodies) and antibodies cross-reacting  
therewith in a biological fluid of a patient or  
sepsis risk patient are determined and conclusions  
are drawn from the presence and/or amount thereof  
15 with regard to the presence, the expected course,  
the severity or the success of a therapy of the  
inflammatory disease or sepsis or with regard to  
the risk of a sepsis risk patient.
- 20 2. Method according to Claim 1, characterized in that  
anti-AG<sub>M1</sub> and/or anti-G<sub>M1</sub> (auto)antibodies of the  
IgG and/or IgA type are determined.
3. Method according to Claim 1 or 2, characterized in  
25 that the biological fluid is blood, a blood  
fraction or a secretion.
4. Method according to any of Claims 1 to 3,  
30 characterized in that the determination is carried  
out with the aid of a ligand binding assay of the  
sandwich type or of the competitive type or of an  
agglutination assay.

5. Method according to any of Claims 1 to 4, characterized in that the determination of the antibodies in a blood sample of a sepsis risk patient is carried out after prior in vivo and/or in vitro stimulation of the antibody production.
6. Method according to any of Claims 1 to 5, characterized in that it is carried out as part of a multiparameter determination, in which at least one further inflammation or infection parameter is simultaneously determined and in which a measured result in the form of a set of at least two measured parameters is obtained, which result is evaluated for the fine diagnosis of sepsis.
7. Method according to Claim 6, characterized in that, in addition to the anti-ganglioside autoantibodies, at least one further parameter which is selected from the group consisting of the proteins procalcitonin, CA 125, CA 19-9, S100B, S100A proteins, LASP-1, soluble cytokeratin fragments, in particular CYFRA 21, TPS and/or soluble cytokeratin-1 fragments (sCY1F), the peptides inflammin and CHP, peptide prohormones, glycine N-acyltransferase (GNAT), carbamoylphosphate synthetase 1 (CPS 1) and the C-reactive protein (CRP) or fragments thereof is determined as part of the multiparameter determination.
8. Method according to Claim 6 or 7, characterized in that the multiparameter determination is carried out as a simultaneous determination by means of a

chip technology measuring apparatus or of an immunochromatographic measuring apparatus.

- 5 9. Method according to Claim 8, characterized in that the evaluation of the complex measured result obtained using the measuring apparatus is carried out with the aid of a computer program.
- 10 10. Method for the quality control of donor blood for medical purposes, in which the presence and/or amount of anti-asialo-G<sub>M1</sub> antibodies (anti-AG<sub>M1</sub> antibodies) and antibodies cross-reacting therewith, in particular anti-G<sub>M1</sub> antibodies, are determined in a sample of the donor blood and, in  
15 the case of positive detection of such antibodies,
  - the donor blood is rejected or
  - is subjected to an affinity purification for removing the antibodies determined and is administered to a patient only after a subsequent  
20 further antibody determination with a negative result.
- 25 11. Method according to Claim 10, in which the donor blood investigated is banked blood from a blood bank or freshly obtained donor blood.
- 30 12. Method for discovering and for detecting individual substances or constituents of mixtures of substances, which have structural properties which simulate ganglioside structures, in which individual substances or mixtures of substances to be investigated are tested in an assay system which is based on the binding of anti-ganglioside

antibodies to a specific binder and the detection of bound antibodies, a competitive reduction of the antibody binding to the specific binder in the presence of the substance to be investigated being regarded as an indication of

5

- antibody-blocking properties of the substance or

10

- a potential risk of the substance owing to an antigen effect with initiation of the production of anti-AG<sub>M1</sub> antibody or antibodies cross-reacting therewith in humans.

15

13. Method according to Claim 12, in which the individual substances or mixtures of substances which are used for human or animal nutrition and/or are administered to humans for medical or cosmetic reasons are tested.